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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,283	09/27/2000	John A. Giordano	22920.0003	6590

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EXAMINER

WANG, SHENGJUN

ART UNIT- PAPER NUMBER

1617

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,283

Applicant(s)

GIORDANO ET AL.

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 14-20, 22-30, 36, 38, 41 and 117-136 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1, 14-20, 22-30, 36, 38, 41 and 117-136 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other:

DETAILED ACTION

The Request for a Continued Examination (RCE) under 37 CFR 1.114 filed on December 13, 2002 based on parent Application No. 09/671283 is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 14-15, 18-20, 22-30, 30, 38, 41, 117-120, 122 and 124-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128).
3. Riley teaches an supplemental nutrient oral daily dosage composition comprising about 0.7 to about 15 mg Vitamin B1, about 0.7 to about 15 mg of vitamin B2, about 2 to 100 mg vitamin B6, about 6 to about 100 mg niacin, about 50 to about 800 mcg foliate (in the form of folic acid), about 4 to about 50 mg of pantothenic acid (in the for of d-calcium pantothenate), about 0.5 to about 40 mcg vitamin B12, about 5 to about 300 mcg biotin, about 5 to about 30 mg of zinc, about 10 to about 200 mcg selenium (in the form of L-selenomethionine), about 10 to about 300 mcg chromium, about 20 to about 1,000 mg vitamin C, about 5 to about 2,000 mg vitamin E. See, particularly, claim 1 and tables 2 and 3.
4. Riley does not teach expressly that the amount of folic acid is at least about 800 mcg, or the particular amounts range of each and every ingredients.

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5. However, Wakat teaches that for supplemental purpose, folic acid may be employed in the range of 0.35 mg to 10 mg. See, particularly, claims 1-3.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ more than 800 mcg of folic acid in an oral dosage form.

A person of ordinary skill in the art would have been motivated to employ more than 800 mcg of folic acid in an oral dosage form because folic acid are known to be supplemented up to 10 mg. Further, optimization of the amounts of active ingredients in a nutrient or therapeutical composition is within the skill of the artisan, especially within a known range. such optimization is considered to be an optimization of a result effective parameter, which is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128), for reasons set forth above, and in further view of McLeod (US 5,898,036).

7. Riley and Wakat do not teach expressly the particular chromium salts herein. However, McLeod teaches that chromium chloride, or chromium picolinate are known chromium salt useful as chromium supplements. See particularly, column 5, lines 52-57. one of ordinary skill in the art would have been motivated to employ any chromium salt (e.g., picolinate or chloride) in the composition of Riley because a skilled artisan possessing a pharmaceutical active, also possesses the salts, acids and esters of the said active. Employing of a known salt, acid, and ester of a known compound in lieu of the compound itself is within the skill of the artisan. Moreover,

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the skilled artisan would expected the salts, acids esters of a known compound to exhibit therapeutical effects similar to those of the compounds itself.

8. Claim 121 is rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128), for reasons set forth above, and in further view of Anderson (US 5,278,329).

9. Riley and Wakat do not teach expressly the particular zinc salts herein. However, Anderson teaches that zinc L-methionine is a known ~~chromium~~^{zinc} salt useful as zinc supplements. See particularly, the abstract, column 1, line 5 bridging column 2, line 20, and the claims. One of ordinary skill in the art would have been motivated to employ any known zinc salt (e.g., L-methionine) in the composition of Riley because a skilled artisan possessing a pharmaceutical active, also possesses the salts, acids and esters of the said active. Employing of a known salt, acid, and ester of a known compound in lieu of the compound itself is within the skill of the artisan. Moreover, the skilled artisan would expected the salts, acids esters of a known compound to exhibit therapeutical effects similar to those of the compounds itself.

Response to the Arguments

Applicants' amendments and remarks submitted November 13, 2002, and December 13, 2002 have been fully considered, but are not persuasive for reasons set forth above.

Applicants' arguments are moot in view of the new ground rejection set forth above. Regarding the remarks about the optimization of the amounts of each and every ingredients in a nutrient or therapeutical composition, note the claimed amounts are within the known range employed in the art. Since the art provide clear guidance, such optimization is considered to be

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an optimization of a result effective parameter, which is considered within the skill of the artisan.

See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

February 20, 2003